AVITA Medical Announces Topline Results from Pivotal Trial in Patients with Soft-Tissue Injuries using the RECELL® System

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- *AVITA Medical plans to submit PMA supplement for this new indication to FDA by the end of 2022*

VALENCIA, Calif. and MELBOURNE, Australia, Aug. 11, 2022 (GLOBE NEWSWIRE) -- AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH) (Company), a regenerative medicine company that is developing and commercializing a technology platform that enables point-of-care autologous skin restoration for multiple unmet needs, today announced topline results from its pivotal randomized, controlled trial evaluating the safety and effectiveness of the RECELL System combined with meshed autograft for reduction of donor skin harvesting in soft tissue reconstruction. Injuries considered for the clinical trial included any full-thickness acute skin defect, such as degloving or peeled back skin injuries, road rash, surgical wounds, and flesh-eating disease.

“Soft-tissue injuries can be challenging to treat and I am very pleased with the outcomes using RECELL – especially the use of less donor skin when treating a variety of injuries,” said Dr. Steven E. Mapula, Assistant Professor of Surgery TCU and Division Chief of Plastic Surgery at John Peter Smith Hospital. “Following FDA approval, I look forward to utilizing RECELL broadly to help patients with a wide variety of soft-tissue injuries.”

The study design included co-primary endpoints, based on pairwise comparisons where each subject received both RECELL used in combination with widely-meshed skin grafting and the Control treatment of conventional skin grafting; one endpoint had a hypothesis of superiority for donor skin sparing and the other co-primary endpoint had a hypothesis of non-inferiority for healing. Preliminary review of adverse events shows consistency with our years of prior RECELL experience, reinforcing the product’s compelling safety profile. The primary study outcomes are as follows:

- The donor sparing endpoint was met, showing a superior ratio of treated injury area to donor site area ($p<0.001$) with RECELL versus Control
- The healing endpoint did not reach pre-specified statistical non-inferiority, however, observed values for healing with RECELL were the same or slightly better than Control

“Our study has shown statistically superior donor sparing and comparable healing rates for RECELL treatment of soft tissue injuries and we are confident in moving forward with our plan for a PMA submission later this year,” said Dr. Mike Perry, Chief Executive Officer of AVITA Medical. “The RECELL System has been used to effectively treat serious burn injuries and we anticipate that the RECELL System will be well-positioned to treat patients with soft-tissue injuries, pending FDA review and approval.”

The Company also plans to submit detailed results from the trial for peer-reviewed publication.

Skin grafting is the standard of care for soft tissue reconstruction, including post-trauma and post-surgical skin reconstruction. Skin grafting requires the harvesting of donor skin, resulting in an additional wound to the patient. Significant pain, delayed healing, risk of infection, the need for multiple procedures, discoloration and scarring are associated with donor site wounds.[i] The total addressable market (“TAM”) for soft tissue repair is approximately $1 billion and more than twice as large as the TAM for burns. Further, if FDA approved, the existing reimbursement codes utilized for burn treatment with the RECELL System will apply to this indication.

ABOUT AVITA MEDICAL, INC.
AVITA Medical, Inc. is a regenerative medicine company with a technology platform positioned to address unmet medical needs in burns, chronic wounds, and aesthetics indications. AVITA Medical Inc.’s patented, and proprietary collection and application technology provides innovative treatment solutions derived from the regenerative properties of a patient’s own skin. The Company’s lead product is the RECELL® System, a device that enables healthcare professionals to Spray-On Skin™ Cells using a small sample of the patient’s own skin to create an autologous suspension. The RES® Regenerative Epidermal Suspension™ is then sprayed onto the areas of the patient requiring treatment to regenerate natural healthy epidermis.

AVITA Medicals’ first U.S. product, the RECELL System, was approved by the U.S. Food and Drug Administration (FDA) in September 2018. The RECELL System is approved for acute partial-thickness thermal burn wounds in patients 18 years of age and older or application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric and adult patients. In February 2022, the FDA reviewed and approved the PMA supplement for RECELL Autologous Cell Harvesting Device, an enhanced RECELL System aimed at providing clinicians a more efficient user experience and simplified workflow.

The RECELL System is used to prepare Spray-On Skin™ Cells using a small amount of a patient’s own skin, providing a new way to treat severe burns, while significantly reducing the amount of donor skin required. The RECELL System is designed to be used at the point of care alone or in combination with autografts depending on the depth of the burn injury. Compelling data from randomized, controlled clinical trials conducted at major U.S. burn centers and real-world use in more than 15,000 patients globally, reinforce that the RECELL System is a significant advancement over the current standard of care for burn patients and offers benefits in clinical outcomes and cost savings. Healthcare professionals should read the INSTRUCTIONS FOR USE - RECELL Autologous Cell Harvesting Device (https://recellsystem.com/) for a full description of indications for use and important safety information including contraindications, warnings, and precautions.

In international markets, our products are approved under the RECELL System brand to promote skin healing in a wide range of applications including burns, chronic wounds, and aesthetics. The RECELL System is TGA-registered in Australia, received CE-mark approval in Europe, and received Japan’s Pharmaceuticals and Medical Devices Act (PMDA) approval for burns in Japan.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This press release includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as "anticipate," "expect," "intend," "could," "may," "will," "believe," "estimate," "look forward," "forecast," "goal," "target," "project," "continue," "outlook," "guidance," "future," other words of similar meaning and the use of future dates. Forward-looking statements in this press release include, but are not limited to, statements concerning, among other things, our ongoing clinical trials and product development activities, regulatory approval of our products, the potential for future growth in our business, and our ability to achieve our key strategic, operational, and financial goal. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Each forward-looking statement contained in this press release is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, the timing and realization of regulatory approvals of our products; physician acceptance, endorsement, and use of our products; failure to achieve the anticipated benefits from approval of our products; the effect of regulatory actions; product liability claims; risks associated with international operations and expansion; and other business effects, including the effects of industry, economic or political conditions outside of the company's control. Investors should not place considerable reliance on the forward-looking statements contained in this press release. Investors are encouraged to read our publicly available filings for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this release, and we undertake no obligation to update or revise any of these statements.

This press release was authorized by the review committee of AVITA Medical, Inc.

FOR FURTHER INFORMATION:

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[i] Ter Horst B, Chouhan G, Moiemen NS, Grover LM. Advances in keratinocyte delivery in burn wound care. Advanced drug delivery reviews. 2018 Jan 1; 123:18-32.